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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/041,236 03/11/98 LUO

Y EX98-001

HM22/0911

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EXAMINER

LEE, L

ART UNIT

PAPER NUMBER

1645

18

DATE MAILED:

09/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/041,236

Applicant(s)
Luo et al

Examiner
Li Lee

Group Art Unit
1645



☒ Responsive to communication(s) filed on 8/21/00 and 8/29/00

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 10-13 and 19-22 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☒ Claim(s) 10-13 is/are allowed.

☒ Claim(s) 19-22 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☒ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Art Unit: 1645

DETAILED ACTION

1. Applicant's response filed on Aug 21, 2000 (Paper Number 15) and the amendment filed on Aug 29, 2000 have been received and entered. Claims 10-13 and 19-22 are pending in the instant application.
2. The rejection of claims 10-13 under 35 U.S.C. 101 and under 35 U.S.C. 112, first paragraph is withdrawn in view of applicant's remarks that the polypeptide Semaphorin K1 can be used to regulate nerve and immune cell function.
3. Claims 10-13 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 19-22, directed to the process of using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Process claims 19-22 hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 1645

Claims 19-22 are indefinite for using the terms "a cellular physiology" and "the cell's physiology". The specification and the claims do not clearly define what physical characteristics and properties are the cellular physiology which can be modulated by an agent. Without clearly defined a cellular physiology, ^{of} one ordinary skill in the art can not determine ~~when~~ the bounds and metes of the claimed invention ~~can be met~~. Claims 19-22 are further indefinite for using the term "an agent which modulates activity". It appears that the agent itself is the sema K1 polypeptide. It is not clear how a sema K1 polypeptide agent can modulate a sema K1 activity.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of enhancing organotypic neurite outgrowth from damaged neurons undergoing nerve fiber atrophy by contacting the sema K1 polypeptide with the nerve cells, does not reasonably provide enablement for a method for modulating any cell physiology in any cell by contacting a sema K1 polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The claims recite a method for modulating a cellular physiology in a cell by contacting a sema K1 polypeptide. This encompasses modulating any cellular physiology activity in any cell by contacting a sema K1 polypeptide with the cell. However, the specification only teaches the

Art Unit: 1645

method of enhancing organotypic neurite outgrowth from damaged neurons undergoing nerve fiber atrophy by contacting the sema K1 polypeptide with the damaged cells. The specification does not provide guidance as to any other methods which can modulate any cellular physiology activity in any cell by contacting a sema K1 polypeptide nor does the specification disclose specific characteristics for such methods. The art indicates that modulating a cellular physiology activity by a protein in a cell is empirically determined. There is no known or ~~disclosure~~ ^{disclosed} correlation between the method for enhancing organotypic neurite outgrowth from damaged neurons by contacting the sema K1 polypeptide and other method for modulating a cellular physiology activity in a cell using the same polypeptide. Furthermore, there is no additional disclosure of physical and/or chemical properties for the cellular physiology activity ^{which} can be modulated other than ~~the~~ enhancing organotypic neurite outgrowth from damaged neurons. Without such information, one skilled in the art could not predict which method out of the large number of known methods for modulating a cellular physiology would have modulated a cellular physiology in a manner required by the claimed method and, accordingly, one skilled in the art would be required to perform undue experimentation to identify any other methods that would modulate a cellular physiology by contacting a sema K1 polypeptide and to detect any cellular physiology change that would be caused by a sema K1. Therefore, one skilled in the art could not make the invention without undue experimentation.

Art Unit: 1645

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Status of Claims

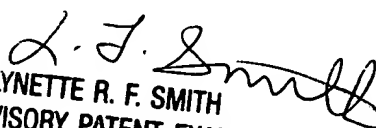
7. Claims 10-13 are allowable. Claims 19-22 stand rejected.

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1645 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Li Lee whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

Li Lee
September 7, 2000


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER